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VIA CM/ECF

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July 9, 2021

The Honorable Maryellen Noreika
U.S. District Court for the District of Delaware
J. Caleb Boggs Federal Building
844 N. King Street
Wilmington, DE 19801-3555

Re: *Aether Therapeutics Inc. v. AstraZeneca AB, et al*., C.A. No. 20-381-MN

***Aether Therapeutics Inc. v. RedHill Biopharma Inc*., C.A. No. 21-248-MN**

Dear Judge Noreika:

Plaintiff Aether Therapeutics Inc. requests the Court's assistance in resolving a time-sensitive issue relating to the claim construction process, specifically, whether Defendants' indefiniteness defense should be resolved at trial rather than as part of claim construction.

This case involves four patents: U.S. Patent Nos. 6,713,488 (the "'488 Patent"); 8,748,448 (the "'448 Patent", asserted only against Defendant RedHill Biopharma Inc.); 8,883,817 (the "'817 Patent"); and 9,061,024 (the "'024 Patent"). Per the scheduling order, Plaintiff provided its opening claim construction brief with proposed constructions for two terms – "analog" and "unit dosage." Defendants responded with a thirty (30) page answering brief, with fifteen (15) pages devoted to arguing that the terms "naloxone analog" and "naltrexone analog" were indefinite. Defendants supported this argument with a forty (40) page declaration from an alleged expert that had not previously been disclosed to Plaintiff.

Although Defendants initially proposed six indefinite terms[1], Defendants agreed not to proceed on four of these terms during claim construction. Defendants now argue that indefiniteness – of two of these terms – should be resolved at claim construction and not trial, while passing on the indefiniteness argument for the other four terms which will, assumedly, be

[1] Defendants proposed the following four terms were also indefinite: "an amount sufficient to substantially inhibit peripheral effects, and insufficient to block substantial central effects of the opioid agonist in the subject" (the '817 Patent, claim 1); "an amount sufficient to produce nearly complete inhibition of peripheral effects, and insufficient to block substantial central effects, of the opioid agonist in the subject" ('817 Patent, claim 20); "an amount sufficient to substantially inhibit peripheral effects, and insufficient to block substantial central effects of the opioid agonist in the subject" ('024 Patent, claim 1); and "an amount of 6β-naltrexol equivalent to the amount of neutral opioid antagonist " ('024 Patent, claim 1).

determined at trial. Determining two of the six indefinite terms at the claim construction stage is a waste of time and judicial resources, since the other terms for which Defendants' claim are indefinite will still need to be argued. Further, it is unclear why Defendants chose to proceed on two of these terms, while agreeing to hold any indefiniteness arguments for the other four.

This position is in direct contrast to previous arguments made by Defendants, in particular, AstraZeneca AB, in recent litigation, wherein AstraZeneca AB, as ***Plaintiff***, argued that ***indefiniteness should be resolved at trial*** and is not a claim construction issue. *See AstraZeneca AB et al. v. Alembic Pharmaceuticals Limited, et al*., C.A. No. 20-202-RGA, D.I. 92, correspondence filed with the Court on December 16, 2020, attached hereto as Exhibit A (emphasis added). Now, Defendants argue the exact opposite – that indefiniteness should be argued at claim construction. Frankly, Defendants should pick their poison.

The arguments made by AstraZeneca AB in C.A. No. 20-202-RGA are equally applicable to those made here by Aether. First, indefiniteness is a merits issue, not a claim construction issue. Second, fact and expert discovery will bear directly on any indefiniteness defense, and Plaintiff should be afforded the opportunity for complete discovery before indefiniteness is briefed and decided on the merits. Indeed, Defendants in this case concede that further discovery is required, and its investigation is ongoing, as Defendants state in their invalidity contentions that their expert reports on invalidity will set forth a more detailed discussion on indefiniteness. *See* D.I. 67-1 at 22. As such, Defendants should not be permitted to file what is effectively a summary judgment motion before fact and expert discovery are complete. Third, Defendants' indefiniteness allegations are premised on the details of Plaintiff's infringement case, and infringement will not be adjudicated until trial, based on information developed during fact and expert discovery.

In C.A. No. 20-202-RGA, Judge Richard G. Andrews entered the following oral order denying without prejudice Defendants' indefiniteness argument and postponing addressing the issue until after *Markman*:

22	05/12/2021	ORAL ORDER: Having reviewed the joint claim construction brief (D.I. 114), and believing that resolution of the issues raised would not benefit from oral argument, the Markman hearing scheduled for May 13th is CANCELLED. The disputed term two or more pharmaceutical diluents is given its plain meaning. The Defendants argument that pharmaceutical diluents/disintegrants/solubilizing agents/lubricants are indefinite is DENIED without prejudice to Defendants raising the argument based on evidence at some later time. Ordered by Judge Richard G. Andrews on 5/12/2021. (nms) (Entered: 05/12/2021)

Plaintiff requests the same relief here – to deny Defendants' indefiniteness arguments for "naloxone analog" and "naltrexone analog", without prejudice, until the completion of fact and expert discovery. Plaintiff's position is supported by precedent, because District Courts throughout the country have generally been reluctant to consider whether a patent is indefinite at the claim construction phase, rather than at the summary judgment phase. *Junker v. Med. Components, Inc.*, No. CV 13-4606, 2017 U.S. Dist. LEXIS 179955, at *5-6, (E.D. Pa. Oct. 31, 2017). In fact, the Court relies on the specification during claim construction and gives claims "their broadest reasonable construction in light of the specification as it would be interpreted by one of ordinary skill in the art." *Innovative Office Prods. V. SpaceCo, Inc.*, 2007 U.S. Dist. LEXIS 62296, at *7-8 (E.D. Pa. 2007), quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc), *cert denied*, 546 U.S. 1170 (2006). Further, several well-settled principles tend to discourage rulings on indefiniteness at the *Markman* stage, including the high burden of proof a defendant must satisfy as well as an indefiniteness ruling's dispositive effect, which is more appropriately addressed at summary judgment. *CSB-Sys. Int'l Inc. v. SAP Am., Inc.*, 2011 U.S. Dist. LEXIS 83462 at *51-53 (E.D. Pa. July 28, 2011).

Given the substantive arguments made by Defendants, that are not related to claim construction, Plaintiff requests the Court to issue a notation on the docket indicating that indefiniteness will be held over until after the completion of discovery. The *Markman* hearing scheduled for August 30, 2021, would then address one term – "unit dosage." In the alternative, Plaintiff requests a telephonic status call prior to substantial time being spent on briefing this issue.

Respectfully submitted,
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cc: All Counsel of Record (via CM/ECF)